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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,130	02/20/2002	Richard B. Meagher	21099.0074U2	6995

23859 7590 10/19/2004

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EXAMINER	
OUSPENSKI, ILIA I	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/079,130	MEAGHER ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-147* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-147* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1 – 147 are pending.

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Restriction Requirement

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1 – 34, 42, 112 – 121, and 130 – 138, drawn to a hybridoma cell or a population of hybridoma cells, classified in Class 435, subclass 326.

II. Claims 35 – 41 and 88 – 91, drawn to a method of making a hybridoma cell, classified in Class 435, subclass 449.

III. Claims 43 – 55 and 110, drawn to a B cell comprising a vector encoding Igα or Igβ, classified in Class 435, subclass 455.

IV. Claims 56 – 59, drawn to a method of making a B cell comprising a vector encoding Igα or Igβ, classified in Class 435, subclass 326.

V. Claims 60 – 67, drawn to a myeloma cell comprising a vector encoding Igα or Igβ, classified in Class 435, subclass 455.

VI. Claims 68 – 69, drawn to a method of making a myeloma cell comprising a vector encoding Igα or Igβ, classified in Class 435, subclass 326.

VII. Claims 70 – 73, 76 – 79, and 82 – 85, drawn to a method of making a monoclonal antibody, classified in Class 435, subclass 70.21.

VIII. Claims 74 – 75, 80 – 81, and 86 – 87, drawn to a monoclonal antibody, classified in Class 530, subclass 388.1.

IX. Claims 92 – 97, 105 – 106, and 109, drawn to a transgenic animal comprising a vector encoding Igα or Igβ, classified in Class 800, subclass 13.

X. Claims 98 – 104, drawn to a method of generating a transgenic animal comprising a vector encoding Igα or Igβ, classified in Class 800, subclass 21.

XI. Claims 107 – 108, drawn to a method of identifying a cell that produces a monoclonal antibody that recognizes a specific antigen, classified in Class 435, subclass 7.1.

XII. Claim 111, drawn to a hematopoietic cell comprising a vector encoding Igα or Igβ, classified in Class 435, subclass 455.

XIII. Claims 122 – 129 and 139 – 147, drawn to a population of plasma cells comprising a vector encoding Igα or Igβ, classified in Class 435, subclass 326.

4. Groups I, III, V, VIII, IX, XII, and XIII are different products. Hybridoma cells, B cells, myeloma cells, monoclonal antibodies, transgenic animals, hematopoietic cells and plasma cells differ with respect to their structures and physicochemical properties

and require non-coextensive searches. Therefore, each product is patentably distinct, and searching of these Inventions would impose an undue burden.

Groups II, IV, VI, VII, X, and XI are different methods. The methods differ with respect to ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct. Furthermore, the distinct ingredients, method steps, and/or endpoints require separate and distinct searches. As such, it would be burdensome to search these Inventions together.

Groups I and VII *are related as product and process of using.* The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the monoclonal antibodies of Group VII can be made by phage display, in addition to the hybridoma cells of Group I.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

6. This application contains claims directed to the following patentably distinct species of the claimed Inventions I - XIII, wherein the surface-expressed antibody receptor is:

(A) Igα, or

(B) Igβ.

These species are distinct because their structures, physicochemical properties and mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Furthermore, the examination of these species would require different searches in the scientific literature.

Applicant is required under 35 USC 121 to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable. Currently, claim 17, for example, is generic.

7. This application contains claims directed to the following patentably distinct species of the claimed Inventions I – III, V, VI, and IX, wherein the Igα receptor comprises mutations:

(A) Y176F,

(B) Y182F,

(C) Y193F, or

(D) Y204F.

These species are distinct because their structures, physicochemical properties and mode of action are different. Furthermore, the examination of these species would require different searches in the scientific literature.

Applicant is required under 35 USC 121 to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable. Currently, claim 23, for example, is generic.

8. This application contains claims directed to the following patentably distinct species of the claimed Inventions I – III, V, VI, and IX, wherein the Igβ receptor comprises mutations:

(A) Y190F, or

(B) Y206F.

These species are distinct because their structures, physicochemical properties and mode of action are different. Furthermore, the examination of these species would require different searches in the scientific literature.

Applicant is required under 35 USC 121 to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable. Currently, claim 23, for example, is generic.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI
Examiner
Art Unit 1644

September 7, 2004

Phillip Gambel
PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
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9/05/04